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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/640,853

08/13/2003

Randall V. Sparer

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7590

08/25/2009

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/640,853	<b>Applicant(s)</b> SPARER ET AL.	
	<b>Examiner</b> JAMES W. ROGERS	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-75 and 78-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20-75 and 78-88 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/11/2009 and 07/30/2009</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicants amendments to the claims filed 03/11/2009 have been entered.

The declaration under 37 CFR 1.132 filed 03/11/2009 is noted, this declaration was filed to support the patentability of the claims in the application, however no opinion was offered by Mr. Christopher M. Hobot in regards to how the data provided differentiates their claims from the cited prior art. Instead applicant's consul as discussed below used the data provided by Mr. Hobot in their arguments, therefore the data provided in the declaration has been considered below by the examiner as part of the response to applicants arguments.

### ***Response to Arguments***

**Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252), for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action filed 09/11/2008.**

**Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1), for the reasons set forth in the previous office action filed 09/11/2008.**

Applicant's arguments filed 03/11/2009 have been fully considered but they are not persuasive.

Applicant's assert that each reference above fails to specifically point out and distinctly set forth each and every recited feature within the claims. Applicants assert that the examiner has given no support for his assumption that the polymers described in each reference will have the same solubility parameters especially in view of the declaration provided by Mr. Hobot that purports to show how the solubility parameters can vary greatly even within the same class of copolymers. Applicants further contend that none of the references describe the discretionary and cognitive step of selecting polymers based upon their solubility parameters. Applicants go on to state that the examiner cannot simply ignore the mental step of selecting polymers based upon their solubility properties simply because it is a mental process.

The examiner respectfully disagrees with applicant's argument above. Applicants claims as currently amended only require that the polymer blend comprise a first polymer selected from a hydrophobic cellulose, a polyurethane or poly(ethylene-co-(meth)acrylate) and a second polymer that is miscible with it, the types of second polymers are described throughout the claims and specification. In order to conduct his search the examiner searched for the same polymers that would meet the claimed blend, the examiner can only search for the claimed subject matter. For examination purposes the examiner concluded that the same polymer will inherently have the same properties. Since the polymers within the references above are within the scope of applicants claimed polymers it is assumed that the properties of the polymers are the same including their differences in solubility parameters. While applicants do show in their declaration that the calculated solubility parameter for a copolymer can vary

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depending on the molar ratio of its constituent monomer units, there is no such recitation within their own claims on either the solubility parameter of the first polymer or the molar ratio of that polymer. Since there is no distinguishing physical characteristic set forth in the claims that would distinguish the first polymer as having a different solubility parameter than the cited reference the examiner must consider that the same polymer as claimed by applicants will have the same properties including its solubility parameter. The examiner notes that within their arguments they only discuss the solubility parameter of polyurethane (PU) however the first polymer in the blend can also include a hydrophobic cellulose and poly(ethylene-co-(meth)acrylate). Applicants do discuss in their arguments from 10/640,702 the solubility parameters of poly(ethylene-co-(meth)acrylate) and in 10/640,714 applicants discuss the solubility parameters of the hydrophobic cellulose acetate butyrate (CAB), since these copolymers are relevant to the claimed invention for application 10/640,853 the examiner included them in the remarks below. It is noted by the examiner that the solubility parameter range provided by applicants for the copolymer poly(ethylene-co-(meth)acrylate) provides a range between the two constituent homopolymers solubility parameters, however since a copolymer cannot contain just one homopolymer nor could a polymer containing a functionalized end unit derived from a monomer or a short chain oligomer be considered a copolymer, the relevance of providing these extreme solubility end values for the copolymer of  $15.8 \text{ J}^{1/2}/\text{cm}^{3/2}$  and  $22.4 \text{ J}^{1/2}/\text{cm}^{3/2}$  is unclear. Clearly a more likely range of molar amounts for each constituent monomer for a copolymer would range anywhere from 10:90 or 90:10 for ethylene and methacrylate respectfully. The examiner also

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notes that in a similar manner applicants have calculated the solubility parameter of CAB as a range between the parameters of cellulose acetate and cellulose tributyrate. Furthermore it is noted by the examiner that such solubility parameters are not based on lab results but calculations and as recited within the disclosure of D.W. Van Krevelen provided by applicants in appendix A, the publication clearly notes the limited accuracy of solubility parameters for polymers and further teaches that they should only be treated as a rough estimates. See page 208 lines 17-21 and page 212 lines 5-8. Since solubility parameters for polymers can only be considered as rough estimates and not very accurate this would seem to cast some doubt on the significance of arguing data points derived from calculated solubility parameters. Furthermore it is noted by the examiner that the calculated values of poly(ethylene-co-(meth)acrylate) in molar ratios of 1:1 and 4:1 are within  $0.9 \text{ J}^{1/2}/\text{cm}^{3/2}$  from each other, thus the solubility parameters are fairly close even though the molar ratios are fairly different. Lastly the examiner notes that he can also pull solubility parameters for the polymers taught within the references above, such as Hossainey and show that the polymers are within applicants claimed solubility difference range. For instance table 7.5 in van Krevelen recites calculated solubility parameters of 16.0 for polyethylene and 19.9 for poly(methyl acrylate), thus a copolymer would have a calculated solubility parameter between 16.0-19.9 using applicants calculation method, poly(methyl methacrylate) (PMMA) has a solubility parameter of 19.0, the difference between PMMA and the solubility range for the copolymer is  $3 \text{ J}^{1/2}/\text{cm}^{3/2}$  or less. Thus since Hossainey teaches the use of poly(ethylene-co-(meth)acrylate) in combination with another polymer such as PMMA in

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a blend the examiner can consider the limitation on the difference of solubility parameters met. In a similar manner Sirhan claims the combination of CAB and PVAC, from applicants own description within their specification CAB and PVAC have solubility parameters of 22 and 21  $\text{J}^{1/2}/\text{cm}^{3/2}$ , the difference between them is only 1  $\text{J}^{1/2}/\text{cm}^{3/2}$ , within applicants claimed solubility difference range. The references cited above each teach a process to make the same polymer blend claimed, the blend contains the same polymers and active ingredients, since the ingredients are the same and are capable of being blended together they are miscible with each other, therefore it is considered inherent that the limitations on solubility parameter differences are met.

Applicants assert that the references above teach several different classes of polymers, thus applicants surmise that the references each specify a vast number of individual polymer species. Applicants further contend that there is no guidance within the references above to select the same polymer blend claimed by applicants.

Applicants contend that randomly taking polymers from a subgenera listed in the claims of the reference above will not necessarily result in a combination of polymers that are miscible with each other or have the claimed difference in solubility. Applicants further argue that there is no 35 U.S.C. § 112 1st paragraph support within either reference for applicants claimed invention.

The examiner respectfully disagrees. Firstly with respect to Sirhan the polymer blend described is claimed, all US patents are considered valid thus, there is adequate description and 112 1st paragraph support for the claimed polymers. As mentioned numerous times in actions in the past and again herein both the Hossainey and

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Whitbourne references clearly teach the same first and second polymers claimed by applicants. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting applicants claimed second polymer and also claims an active agent that included several cellulose derivatives and polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the claims and the description of the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainey appellants claimed drug delivering polymer blend and the method to produce it. Also in regards to Whitbourne and Hossainey, the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. Furthermore while both the references above teach and claim numerous polymer blends, this only supports the fact that polymer blends are a well known and very mature field. One of ordinary skill in the art would know from the teachings of the references and what is generally well known and established in the art that numerous polymers can be blended or mixed together to form coatings for medical devices. In the same regard applicants specification and claims are also broad in the number of types of polymers that can be blended, but the examiner has concluded that applicants have provided enough written description and



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showed enablement since the field of polymer blends is well known and very mature field, thus there are currently no 112 1<sup>st</sup> paragraph rejections over the breadth of the claims. However applicants argue that a prior art reference which is similar to their claimed invention in that it also describes numerous types of polymer blends, does not teach their claimed blend just because numerous combinations are possible. A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As detailed above the examiner concluded from the prior art that polymer blends used as coatings for medical articles is a very mature field, thus the breadth of the number of possible combinations would not preclude one of ordinary skill in the art from envisioning nearly any combination of polymers that are described as being capable of being blended. Thus the examiner believes there is adequate support and guidance within each reference so that one of ordinary skill in the art would have readily envisaged applicants claimed invention from the teachings of Hossainey and Whitbourne.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments with respect to the 103(a) rejections over Sirhan, Hossainey and Whitbourne have been considered but are moot in view of the new ground(s) of rejection.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed., Elsevier, cited by applicants. This new rejection was necessitated by applicant's amendments to the claims.

Sirhan is disclosed in the previous office action filed 01/29/2009. The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Sirhan discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers

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found within Sirhan in order to calculate which polymers are likely to form blends when mixed together.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1), in view of in view of Coleman et al., Specific interactions and the miscibility of polymer blends, Ch 2, a practical guide to polymer miscibility pages 49-156. This new rejection was necessitated by applicant's amendments to the claims.

The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Coleman is used for the review found throughout chapter 2 on predicting polymer miscibility, while the review of Coleman is far too thorough to detail every aspect of predicting miscibility of polymer blends the reference basically states that the closer two polymers are in their solubility parameter the greater the likelihood that they will be miscible with each other. In fact Coleman discusses a computer program one can use that predicts the solubility parameters of two polymers and can predict, with some degree of accuracy whether the polymers would be miscible. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of Coleman it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Sirhan discloses the use of polymer blends but does not describe any method for predicting which polymers would

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be miscible with each other one of ordinary skill in the art could have used solubility parameters or a program as disclosed within Coleman and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close, especially if the program predicted the polymer would be miscible. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Sirhan in order to calculate which polymers are likely to form blends when mixed together.

Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed., Elsevier, cited by applicants. This new rejection was necessitated by applicant's amendments to the claims.

Hossainy is disclosed in the previous office action filed 01/29/2009. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between

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Claims 1-18, 20-75 and 78-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), in view of Van Krevelen, Properties of Polymers, Chapter 7, 3<sup>rd</sup> ed., Elsevier, cited by applicants. This new rejection was necessitated by applicant's amendments to the claims.

Whitbourne is disclosed in the previous office action filed 01/29/2009. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. van Krevelen is used only for the disclosure found

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within that it was well known in the art at the time of applicants claimed invention that two substances with similar solubility properties should be mutually soluble whereas when the difference between the solubility parameters increases the tendency towards dissolution decreases. See page 201 lines 1-15. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, from the disclosure of van Krevelin it was well known in the art that the difference between solubility parameters could be used to predict solubility and therefore also the miscibility of two substances. Since Whitbourne discloses the use of polymer blends but does not describe any method for predicting which polymers would be miscible with each other one of ordinary skill in the art could have used solubility parameters in a table as disclosed within van Krevelen and had a reasonable expectation of success in blending two polymers if their solubility parameters were relatively close. One of ordinary skill in the art would have been motivated to find the solubility parameters of the polymers found within Whitbourne in order to calculate which polymers are likely to form blends when mixed together.

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***Conclusion***

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618